

REMARKS/ARGUMENTS

Claim 9-14 are pending. The claims have been amended for consistency with U.S. practice. Claims 13 and 14 find support in the original claims and on pages 12-13 (bridging paragraph) of the specification. Accordingly, the Applicants do not believe that any new matter has been added. Favorable consideration of this amendment and allowance of this application is respectfully requested.

Rejection—35 U.S.C. §101

Claims 5-8 were rejected under 35 U.S.C. 101 as being non-statutory claims. This rejection is moot.

Rejection—35 U.S.C. §102

Claims 1-4 and 9-12 were rejected under 35 U.S.C. 102(b) as being anticipated by Nagasawa et al., U.S. Patent No. 5,981,557, Nagasawa et al., JP10-212271 (abstract) and Nakajima et al., J. Smooth Muscle Res. 36:69. The rejection of Claims 1-4 is now moot.

Claims 9-12 are directed to treating a subject having impaired gastric accommodation. The cited prior art does not disclose treatment of this class of subjects. Nagasawa et al., U.S. Patent No. '557 describes "restoration effects on dysmotility in the gastrointestinal tract" (see abstract). This document refers to pharmacological data concerning the amelioration of the movements of the gastropyloric vestibular portion (the lower portion of the stomach) and duodena, but is totally silent about whether compounds of formula I exert any effect on the upper portion of the stomach. Medicines that act on the upper portion of the stomach are useful for treating impaired gastric accommodation.

Unlike the claimed method, Nagasawa, JP '271 describes "a treating agent for gastrointestinal tract motion disorders" (see abstract), and Nakajima et al. describes induction

of “gastrointestinal prokinetic action” (abstract) and action which “stimulates gastric motility” (page 80).

Impaired gastric accommodation is distinct from dysmotility in the gastrointestinal tract and from stimulation of gastric motility/prokinetic actions. Tack et al., Gut 52:1271) indicates that:

Functional dyspepsia is a clinical syndrome characterized by chronic or recurrent epigastric pain or discomfort without an identifiable cause by conventional diagnostic means. The pathophysiology of functional dyspepsia seems to be heterogeneous, and suggested mechanisms include delayed gastric emptying, visceral hypersensitivity to distension, impaired gastric accommodation to a meal, abnormal duodenojejunal motility, *Helicobacter pylori* gastritis, or central nervous system dysfunction. (page 1271, first col.)

Several recent studies suggest that impaired accommodation to a meal in an important pathophysiological mechanism in dyspepsia. (page 1271, first col.)

In summary, a slow caloric drinking test can distinguish most severe dyspeptic patients from controls. The end point of the test was **significantly correlated to gastric accommodation, but not to gastric emptying or to sensitivity to distension.** (emphasis added) (page 1276, second col., last paragraph)

As shown above is gastric accommodation is distinct from the disorders or conditions described by the prior art and the prior art does not disclose that compounds of formula I would have any effect on gastric accommodation. Accordingly, this rejection should now be withdrawn, since the prior art does not disclose treating a subject having impaired gastric accommodation.

Conclusion

In view of the amendments and remarks above, the Applicants submit that this application is now in condition for allowance. An early notification to such effect is now respectfully requested.


Respectfully submitted,

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